

CLAIMS

Claim 1 (currently amended): A method for collecting mammalian cells, comprising the steps of:

- (a) providing a tube having an open end and a closed end, that receives cells collected directly from a blood draw;
- (b) preloading compounds and drying the compounds including:
an anticoagulant agent, and
a fixative agent into said tube, said fixative agent selected from the group consisting of:
diazolidinyl urea, imidazolidinyl urea, dimethyol-5,5 dimethylhydantoin, dimethylol urea,
2-bromo-2-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-l-laza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly [methyleneoxy]methyl-l-laza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-l-laza-3,7-dioxabicyclo [3.3.0] octane, quaternary adamantine and combinations thereof, wherein;
- (c) drawing a blood sample into the tube whereby it contacts the dried pre-loaded compounds to yield a final composition wherein the ratio of the volume of any preloaded compounds to the combined volume of the blood sample and the compounds is less than about 2:100, and so that the cells are stabilized directly and immediately upon blood draw.
- (d) placing a closure at said open end of said tube to seal the tube in a manner creating and maintaining a pressure differential between atmospheric pressure outside said tube and a pressure less than atmospheric pressure within said tube, the closure being such that it remains in place throughout blood draw and stabilization of cells;

(e) ~~wherein the preloaded compounds are employed in an amount and concentration sufficient so that after collection of cells from a blood draw in the tube, the ratio of the volume of any preloaded compounds to the combined volume of the cells and the compounds is less than about 2:100, and so that the cells are stabilized directly and immediately upon blood draw.~~

Claim 2 (previously presented): The method of Claim 1, wherein said anticoagulant agent is selected from the group consisting of ethylene diamine tetra acetic acid (EDTA), salts of EDTA, ethylene glycol tetra acetic acid (EGTA), salts of EGTA, hirudin, heparin, citric acid, salts of citric acid, oxalic acid, salts of citric acid, and a combination thereof.

Claim 3 (currently amended): The method of Claim 1, wherein the concentration of said fixative agent preloaded in said tube is less than about 1g of fixative agent per [(*/*)] ml of preloaded compounds.

Claim 4 (currently amended): The method of Claim 1, wherein the concentration of said anticoagulant agent preloaded in said tube is less than about 0.3 g of anticoagulant agent per [*/*] ml of preloaded compounds.

Claim 5 (previously presented): The method of Claim 1, wherein said preloading step further includes preloading a polyacrylic acid into said tube.

Claim 6 (cancelled)

Claim 7 (previously presented): The method of Claim 1, wherein said cells are selected from the group consisting of whole blood, epithelial cells, bone marrow, spinal fluid, abnormal tissue sample in a cellular suspension, and a combination thereof.

Claim 8 (previously presented): The method of Claim 1, further comprising the step of sterilizing said compounds prior to preloading step.

Claim 9 (cancelled)

Claim 10 (previously presented): The method of Claim 1, further comprising the step of providing at least one component selected from the group consisting of an alcohol swab, a gauze, a tube holder, a tourniquet, a glove, other cell collection tube, a needle, a lancet, adhesive strip, syringe, a test strip, a strip containing reagents for cell analysis, a packaging means for storing said at least one component and said collection device to form a kit, and a packaging means for transporting said collection device.

Claims 11-26 (cancelled)

Claim 27 (currently amended): A method for preparing mammalian cells for analysis, said method comprising the steps of:

(a) providing a closed collection container, said container having an internal pressure less than atmospheric pressure outside said container, wherein said collection container contains preloaded compounds including an anticoagulant agent and a fixative agent selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethyolol-5,5

dimethylhydantoin, dimethylol urea, 2-bromo-2.-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5 hydroxymethoxymethyl-l-laza-3, 7-dioxabicyclo [3.3.0] octane, 5-hydroxymethyl-l-laza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-l-laza-3,7-dioxabicyclo [3.3.0] octane, quaternary adamantine and combinations thereof inside said tube; and

(b) drawing a blood sample into the collection container whereby the blood sample contacts the preloaded compounds to yield a final composition collecting said cells in said collection container, wherein after collection of the cells in the container, the ratio of the volume of any preloaded compounds to the combined volume of the final composition cells and the compounds is less than from about 1:100 to about 2:100.

Claim 28 (previously presented): The method of Claim 1, wherein the ratio of the volume of any preloaded compounds to the combined volume of the cells and any preloaded compounds is less than about 1.5:100.

Claim 29 (previously presented): The method Claim 28, wherein the ratio of the volume of any preloaded compounds to the combined volume of the cells and any preloaded compounds is less than about 1:100.

Claim 30 (currently amended): The method of Claim 3, wherein the concentration of said fixative agent preloaded in said tube is less than about 0.75 g of fixative agent per [(/)] ml of preloaded compounds.

Claim 31 (currently amended): The method of Claim 30, wherein the concentration of said fixative agent preloaded in said tube is less than about 0.5 g of fixative agent per [(/)] ml of preloaded compounds.

Claim 32 (currently amended): The method of Claim 4, wherein the concentration of said anticoagulant agent preloaded in said tube is less than about 0.2 g of anticoagulant agent per [(/)] ml of preloaded compounds.

Claim 33 (currently amended): The method of Claim 32, wherein the concentration of said anticoagulant agent preloaded in said tube is less than about 0.15 g of anticoagulant agent per [(/)] ml of preloaded compounds.

Claims 34-39 (cancelled)

Claim 40 (currently amended): A method for preparing mammalian whole blood cells for analysis, said method comprising:

- (a) providing a collection container for receiving a whole blood sample;
- (b) introducing into the collection container preloaded compounds that include an anticoagulant agent and a fixative agent selected from the group consisting of diazolidinyl urea, imidazolidinyl urea and a mixture thereof;
- (c) evacuating the collection container to an internal pressure that is less than atmospheric pressure outside said container;
- (d) drawing a volume of a whole blood sample into the collection container whereby the blood sample contacts the preloaded compounds to yield a final composition, wherein the ratio

of the volume of any preloaded compounds to the volume of the final composition combined
~~volume of the whole blood sample and the compounds~~ is less than about 2:100; and
— (e) ~~mixing the preloaded compounds with the whole blood sample in the collection~~
~~container (10) so that cells of the whole blood sample are contacted with the preloaded~~
~~compounds.~~

Claim 41 (previously presented): The method of Claim 40, wherein the compounds consist essentially of the anticoagulant agent and the fixative agent selected from diazolidinyl urea, imidazolidinyl urea, and a mixture thereof.

Claim 42 (previously presented): The method of Claim 41, wherein the anticoagulant agent is selected from ethylene diamine tetra acetic (EDTA), salts of EDTA, and a mixture thereof.

Claim 43 (currently amended): The method of Claim 42, wherein the anticoagulant agent is $K[Cl]_3$ EDTA present in an amount of less than about 0.3 g of anticoagulant agent per [(/)] ml of preloaded compounds.

Claim 44 (currently amended): The method of Claim 41, wherein the fixative agent consists of diazolidinyl urea present in an amount of less than 1 g of fixative agent per [(/)] ml of preloaded compounds.

Claim 45 (previously presented): The method of Claim 40, said method further comprising storing the whole blood sample in the collection container after mixing and prior to analyzing.

Claim 46 (previously presented): The method of claim 45, wherein said whole blood sample is stored at ambient temperature for a period of at least 3 days prior to analyzing.

Claim 47 (previously presented): The method of Claim 40, said method further comprising transporting the whole blood sample in the collection container from the collection site to the analysis site.

Claim 48 (previously presented): The method of Claim 45, wherein said analyzing includes screening the whole blood cells for HIV.

Claim 49 (currently amended): A method of screening a subject for abnormal cells or tissues, comprising the steps of:

- (a) collecting a cell or tissue sample from said subject using the method of claim 1 device of Claim 14;
- (b) analyzing collected cell or tissue sample for abnormality using a flow cytometer, a hematology analyzer, or a combination thereof; and
- (c) providing the results of analysis for identification.

Claim 50 (previously presented): The method according to claim 49, wherein said abnormal cells or tissues are indicative of a disease selected from the group consisting of HIV, HPV, hepatitis, leukemia, cancer, and a combination thereof.

Claim 51 (cancelled)